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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,956	BADLEY ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/24/05; 3/02/04;3/22/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-16 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-16 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 9, 2005 has been entered.

Amendment Entry

2. Applicant's response filed on November 9, 2005 is acknowledged. Applicant requests reconsideration of arguments in Appeal Brief filed on May 24, 2005. Applicant also requests reconsideration of Interview Summary on March 2, 2004 and Applicant's response filed on June 22, 2004.

Claims Under Prosecution

3. Claims 1-3, 5-16 and 22 are pending in the application and are currently under prosecution.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 7-10, and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schramm (US Patent 5,281,539).

Schramm et al. disclose a method comprising contacting a first surface upon which a displaceable moiety such as an antibody has been reversibly bound, with a sample, wherein analyte in the sample displaces the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a capture antibody is bound which produces a signal, and detecting the signal produced by fluorescence or enzyme labels. Schramm et al. teach that the two surfaces can be on separate or same supports that may be in planar, porous, or particulate surface form (see Abstract, especially column 5, line 51 to column 6, line 2, and column 4, line 42 to column 5, line 4). The analyte may be any one of protein hormones (progesterone or testosterone), nucleic acids, peptides (benzoylecgonine), and any other organic or inorganic species of molecules present in a body fluid sample (see column 3, lines 53-59). The first surface comprises intervening molecules including lectins, receptors, membrane proteins, transport proteins, monoclonal antibodies, immunoglobulins (subtype IgG2bk), polyclonal antibodies (bispecific antigen-binding antibodies), complimentary subunits (immunoglobulins), and analyte analogues (other compounds that competitively bind with the analyte) which bind reversibly or loosely to the displaceable moiety (see column

4, lines 48-62 and column 6, line 62 to column 7, line 3). Schramm et al. disclose using electrodes in a sensor to detect modulation of an electrochemical property of the capture moiety wherein modulation is in the form of a detectable signal. If present, analyte continually displaces the displaceable moiety which is then continually captured by the capture antibody so that the measured signal from the sensors continuously changes, with the concentration of the analyte captured on the sensor (see column 8, lines 27-62 and Figure 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US Patent 5,281,539) in view of Partin et al. (US Patent 5,082,630) and in light of Carter (US Patent 4,608,344).

Schramm et al. has been discussed supra. Schramm et al. differs from the instant invention in failing to teach that the detectable signal comprises the generation or the modulation of, an evanescent or acoustic wave.

Partin et al. disclose a fiber optic detector for use in immune testing. In practice, Partin et al. disclose coating a distal end of an optical fiber or waveguide (first surface) with antibody, then saturating the fiber with fluorescent-tagged drug derivative, i.e. antigen (displaceable moiety). Thereafter, the fiber is exposed to an airborn sample of the analyte, i.e. drug, to be detected. If the analyte is present, the analyte molecules displace some of the bound, fluorescent-tagged derivative, resulting in a decrease (modulation) in signal as detected by a detecting diode. The extent of the decrease is proportional to the concentration of drug molecules in the surrounding environment. See column 4, lines 49-64 and column 4.

Carter et al. explains the concept of measuring evanescent waves in waveguides, i.e. as those used by Partin et al. supra (see especially columns 5-6).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute a waveguide as taught by Partin in light of the teaching of Carter, to capture and detect the signal in the form of an evanescent wave generated in the method of Schramm, because Schramm appears to be generic in the type of detection method used, depending on the labels used, and Partin taught that the optical

fibers and waveguides for use in detection have the advantage of being sensitive detectors even at extremely low concentrations of analyte.

6. Claim 5, 6, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US Patent 5,281,539) in view of Presta et al. (US Patent 6,025,166).

Schramm et al. has been discussed supra. Schramm et al. differs from the instant invention in failing to disclose specifically using fusion protein in claim 5 as a displaceable moiety.

Presta et al. disclose using fusion proteins (chimeric proteins) in competitive displacement assays. Specifically, Presta et al. tested binding specificity of fusion proteins in a cellular environment , wherein the competitive displacement assay was done with iodinated neurotrophins.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the intervening moiety or the displaceable moiety in the method of Schramm et al., with fusion or chimeric proteins as taught by Presta because Presta specifically taught application of fusion proteins in displacement assays such as in the methods of Schramm et al.

Schramm et al. and Presta are silent in teaching mimitopes as analyte analogues in claim 6 or as an intervening moiety in claim 22.

It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute mimitopes as intervening molecules or analyte analogues in the method of Schramm as modified by Presta, because mimitopes

constitute obvious variations of complimentary subunits and analyte analogs taught in the method of Schramm, for use in recognizing specific epitopes in the immunological assay art.

Response to Arguments

7. Applicant's arguments filed 6/22/04 have been fully considered but they are not persuasive.

A) Applicant argues that Schramm et al. fails to anticipate the claimed invention because it is not clear in Schramm how the captured moiety binding to the second surface meets the required limitation which states that, 1) "the capture moiety on the second surface generates a species capable of producing a detectable signal", and 2) "the signal cannot be generated unless and until the displacement moiety is captured on the second surface", since it is not clear how the signal is generated. Applicant specifically contends that the embodiment in Figure 7 uses Clark electrodes as sensors, which are oxygen electrodes, which would not directly detect anything that is bound to the sensor; hence, Applicant concludes that the Figure 7 embodiment in Schramm et al. is not enabling, since it does not describe how the signal is generated, and how the signal depends on the binding of the displaceable moiety to the surface of sensor 2.

In response, at column 8, lines 27-51 of the Schramm reference which explains Figure 7, it is provided that the presence of analyte causes a continuous displacement of displaceable moiety from Sensor 1 for capture of the displaceable moiety into Sensor 2, which results to continuous change of concentration of analyte in each individual

sensor, and the change in concentration of analyte in each sensor including Sensor 2, is manifested as a measured signal. Hence, the displaceable moiety "species" generated in Sensor 2 is capable of producing its distinct detectable signal separate from that in Sensor 1, and the "[detectable, distinct] signal is not generated unless and until the displacement moiety is captured on the second surface. Accordingly, the teaching of Schramm describing Figure 7 appears to read on claim 1.

In as far as use of Clark electrodes in Figure 7, Schramm intends such electrodes as only exemplary for certain embodiments, i.e. "sensors can be electrodes such as Clark electrodes", and does not intend such embodiment to limit the scope of his invention. Additionally, Schramm's disclosure of signal generating means for use in the method in column 4, lines 63-67, includes enzymes, fluorescent molecules, ultraviolet absorbent agents and other compounds capable of conjugation with the analyte, without deletion of the capacity to generate the signal. When using electrodes to detect the detectable signal, the analyte, if present, continually displaces the displaceable moiety and then is continually captured by the capture antibody so that the measured signal from the sensors each continuously and individually changes, with the concentration of the analyte captured on the sensor (see column 8, lines 27-62 and Figure 7). Accordingly, Applicant's argument that the disclosure of Schramm is not enabling for lack of description of how the signal is generated and how the signal depends on the binding of the displaceable moiety to the surface of Sensor 2, is not on point.

B) Applicant argues that the combination of Schramm with Partin is improper and does not render obvious the claimed invention. Applicant specifically contends that the embodiment of Figure 7 does not make use of fluorescence or other optical indicators; rather it uses an electrode in a manner that is not clearly disclosed. Applicant argues that the mere fact that Schramm discloses optical signaling in other embodiments does not stand as a suggestion to use them in the embodiment of Figure 7, and then to modify them to further use the waveguide of Partin in the process.

In response, use of Clark electrodes in Figure 7 of Schramm is only intended as exemplary for certain embodiments, i.e. "sensors can be electrodes such as Clark electrodes", and does not intend such embodiment to limit the scope of his invention. Schramm discloses use of signal generating means in the method in column 4, lines 63-67, which includes enzymes, fluorescent molecules, ultraviolet absorbent agents and other compounds capable of conjugation with the analyte, without deletion of the capacity to generate the signal.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Schramm teaches contacting the first surface upon which a displaceable moiety such as an antibody or analyte has been reversibly bound, with a sample wherein analyte in the sample displaces the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a specific antibody is bound and detecting the signal which can be produced by fluorescence or enzyme labels. Schramm teaches also using electrodes to detect the detectable signal, i.e. sensors, wherein the analyte, if present, continually displaces the displaceable moiety and then is continually captured by the capture antibody so that the measured signal from the sensors continuously changes, with the concentration of the analyte captured on the sensor. Partin in light Carter, is incorporated with the teaching of Schramm only for the teaching of a detectable signal generated by an evanescent or acoustic wave wherein if analyte is present in a sample, the analyte molecules displace some of the bound, fluorescent-tagged derivatives, resulting in a decrease (modulation) in signal as detected by a detecting diode. The extent of the decrease is proportional to the concentration of the analyte. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to capture and detect the signal generated in the method of Schramm using the waveguide as taught by Partin in light of the teaching of Carter, because Schramm appears to be generic in the type of detection method used, depending on the labels used, and Partin taught that the optical fiber for use in detection has the advantage of being sensitive even at extremely low concentrations of analyte.

8. Applicant's arguments filed May 24, 2005 have been fully considered but they are not persuasive. The arguments filed May 24, 2005 also cover the same issues discussed in the Interview Summary of March 2, 2004.

A) Applicant argues that Schramm et al. fails to anticipate the claimed invention because Schramm is not enabling as to Figure 7. Applicant specifically contends that the sensors in Schramm's Figure 7 are said to be electrodes, i.e. Clark electrodes, which are oxygen electrodes, and that they would not directly detect anything that would be bound to the sensor surface, nor appear to have anything to do with the device as disclosed by Schramm. Applicant further argues that there is no description of how signal is generated in the system using Clark electrodes, and how the signal depends on the binding of the displaceable moiety to the surface in Sensor 2.

In response, Applicant's argument that Schramm et al. is not enabling is not on point. Specifically, claim 12 of Applicant's claimed invention recites that "capture of the displaceable moiety by the capture moiety" provides a modulation of an electrochemical property of the capture moiety which provides a detectable signal. In support for this claim, Applicant provides in the disclosure at page 8, first full paragraph and page 13, second full paragraph, wherein the capture moiety is an antibody immobilized to an electrically conductive support (electroactive surface), wherein binding of the displaceable moiety to the capture moiety alters an electrochemical property, i.e. redox potential, of the capture moiety, generating a signal which may be detected by amperometric, voltammetric, or coulometric means. Schramm et al. provides use of Clark electrodes (oxygen electrodes) which are electrochemical sensors that inherently

have electrically conductive support or surfaces for measuring any change of an electrochemical property, i.e. redox potential, manifested by the displacement of the displacement moiety (conjugate) by analyte and binding of the conjugate to the [capture] antibody, wherein a detectable signal is measured by the sensor. Accordingly, Applicant's description of electrochemical application of the method appears to be consonant with the description provided by Schramm et al. at column 8, lines 27-51.

B) Applicant argues that there is no evidence that capture of conjugate 30" at sensor 2 in Schramm's Figure 7 results in the formation of species capable of producing a detectable signal.

In response, a signal in the context of the claimed invention and Schramm et al. is a change from the baseline (background noise) which is always the first signal that provides an indication of binding or capture. Additionally, column 8, lines 27-51 of the Schramm reference which explains Figure 7, provides that the presence of analyte causes a continuous displacement of displaceable moiety from Sensor 1 for capture of the displaceable moiety into Sensor 2, which results to continuous change of concentration of analyte in each individual sensor, and the change in concentration of analyte in each sensor including Sensor 2, is manifested as a measured signal. Hence, the displaceable moiety "species" generated in Sensor 2 is capable of producing its distinct detectable signal separate from that in Sensor 1, and the "[detectable, distinct] signal is not generated unless and until the displacement moiety is captured on the second surface. Additionally at column 5, lines 51-68, Schramm et al. provide that

"upon exposure to substrate solution, the enzyme develops color on the membrane support" and "[U]pon being bound at membrane, the conjugate (displaceable moiety) converts the substrate to a colored product (detectable signal)." As each and every element and function recited and described by Applicant is consonant with the teaching of Schramm, it is said that Schramm et al. anticipates the claimed invention.

C) Applicant argues that claim 2 is not anticipated, as there is no disclosure of a displaceable moiety that is an immunoglobulin.

In response, claim 2 recites that the displaceable moiety is an immunoglobulin or an antigen-binding derivative thereof. Schramm et al. provide at page 4, lines 48-61 that analyte-binding members or antigen-binding members or derivatives of the analyte include any one of "complimentary subunits (immunoglobulins or antigen-binding derivatives), monoclonal antibodies, polyclonal antibodies, ... and *other compounds that selectively and competitively bind with the analyte*". Accordingly, Schramm et al. appears to anticipate claim 2.

D) Applicant argues that claim 3 is not anticipated, as there is no disclosure of a displaceable moiety that is a bispecific antibody or bispecific antigen-binding derivative thereof.

In response, claim 3 recites that the displaceable moiety is a bispecific antibody or bispecific antigen-binding derivative thereof. Schramm et al. provide at page 4, lines 48-61 that analyte-binding members or antigen-binding members or derivatives of the

analyte include any one of "complimentary subunits, monoclonal antibodies, polyclonal antibodies (bispecific antibody or bispecific antigen-binding derivative thereof), ... and *other compounds that selectively and competitively bind with the analyte*". Accordingly, Schramm et al. appears to anticipate claim 3.

E) Applicant argues that claim 8 is not anticipated as there is no disclosure of an analogue of the analyte bound to the first surface (Sensor 1).

In response, claim 8 recites that the intervening molecule is an analogue of the analyte of interest [bound to the first surface]. Schramm et al. provide at page 4, lines 48-61 that [analyte] binding members, i.e. intervening molecules, immobilized on the first and second surfaces include any one of "lectin, receptors, membrane proteins, complimentary subunits, monoclonal antibodies, polyclonal antibodies ... and *other compounds that selectively and competitively bind", i.e. analyte analogue, with the analyte*. Accordingly, Schramm et al. appears to anticipate claim 8.

F) Applicant argues that claim 22 is not anticipated, as there is no disclosure of a mimitope of the analyte of interest bound to Sensor 1.

In response, Appellant's argument is not on point as claim 22 is based on an obviousness rejection in view of a secondary reference.

G) Applicant argues that Schramm et al. fails to anticipate the claimed invention because there is nothing in Schramm which shows any modification of an

electrochemical property of the capture moiety which is required by claim 12. Applicant points out that claim 12 states that capture of the displaceable moiety by the capture moiety directly modulates an electrochemical property of the capture moiety.

In response, claim 12 of Applicant's claimed invention, indeed, states that capture of the displaceable moiety by the capture moiety directly modulates an electrochemical property of the capture moiety which provides a detectable signal. In support for this claim, Applicant provides in the disclosure at page 8, first full paragraph and page 13, second full paragraph, wherein the capture moiety is an antibody immobilized to an electrically conductive support (electroactive surface), wherein binding of the displaceable moiety to the capture moiety alters an electrochemical property, i.e. redox potential, of the capture moiety and wherein signal is generated and detected by amperometric, voltammetric, or coulometric means. Schramm et al. provides use of Clark electrodes (oxygen electrodes) which are electrochemical sensors that inherently have electrically conductive support or surfaces for measuring any change of an electrochemical property, i.e. redox potential, manifested by the displacement of the displacement moiety (conjugate) by analyte and binding of the conjugate to the [capture] antibody, wherein a detectable signal is measured by the sensor. Accordingly, Applicant's description of electrochemical application of the method appears to be consonant with and encompass the description provided by Schramm et al. at column 8, lines 27-51.

H) Applicant argues that the combination of Schramm with Partin is improper and does not render obvious the claimed invention because the relationship of Partin with Schramm is unclear. Applicant specifically contends that the Examiner has not indicated where in Partin there is any disclosure of an evanescent or acoustic wave.

In response, Schramm teaches contacting the first surface upon which a displaceable moiety such as an antibody has been reversibly bound, with a sample wherein analyte in the sample displaces the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a capture antibody is bound and detecting the signal which can be produced by fluorescence or enzyme labels. Partin is incorporated with the teaching of Schramm only for the teaching of a detectable signal generated by an evanescent or acoustic wave wherein if analyte is present in a sample, the analyte molecules displace some of the bound, fluorescent-tagged derivative, resulting in a decrease (modulation) in signal as detected by a detecting diode. The extent of the decrease is proportional to the concentration of the analyte. Partin specifically discloses application of displacement assays that measure modulation of evanescent wave using waveguides at column 2, lines 49-64. All waveguides inherently function in the same way for detecting signal generated by modulation of an evanescent wave. In support for this rebuttal, Examiner points to columns 5-6 of Carter et al. (US Patent 4,608,344) which explains the concept of measuring evanescent wave in waveguides. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to capture and detect the signal generated in the method of Schramm using the waveguide as taught by

Partin because Schramm is generic in the type of detection method used, depending on the labels used, and Partin taught that the optical fibers and waveguides in detection methods have the advantage of being sensitive even at extremely low concentrations of analyte.

l) Applicant argues that Schramm in view of Presta does not render obvious the claimed invention, specifically claims 5, 6, and 22, because Presta fails to remedy the deficiency of Schramm which fails to teach intervening molecules as analogue of the analyte.

In response, Schramm et al. provide at page 4, lines 48-61 that [analyte] binding members, i.e. intervening molecules, immobilized on the first and second surfaces include any one of "lectin, receptors, membrane proteins, complimentary subunits, monoclonal antibodies, polyclonal antibodies ... and *other compounds that selectively and competitively bind", i.e. analyte analogue, with the analyte*. Accordingly, Schramm et al. appears to anticipate claim 8 and the combination of Presta thereto which discloses using fusion proteins (chimeric proteins) in competitive displacement assays, renders obvious the claimed invention. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the intervening moiety or the displaceable moiety in the method of Schramm et al., with fusion or chimeric proteins as taught by Presta because Presta specifically taught application of fusion proteins in displacement assays such as in the methods of Schramm et al. It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to

substitute mimitopes as intervening or displaceable moieties in the method of Schramm and Presta, because mimitopes and fusion proteins constitute obvious variations of binding members or analogs for use in recognizing specific epitopes in the immunological assay art.

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday from 7:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 2, 2006